

**COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr,
doxylamine succinate solution**
Bi-Mart

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bi-Mart 44-014

Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 30 mg
Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - runny nose and sneezing
 - fever
 - sore throat
 - headache
 - minor aches and pains
 - cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for

children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- mL = milliliter; FL OZ = fluid ounce
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- do not take more than 4 doses per 24 hours
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years: do not use

Other information

- **each 30 mL contains:** sodium 18 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, D&C yellow #10, FD&C green #3, FD&C yellow #6, flavors, glycerin, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sucralose

Questions or comments?

1-800-935-6737

Principal Display Panel

BI-MART

Compare to the active ingredients
in Vicks® NyQuil® Cold & Flu
Nighttime Relief*

NIGHTTIME COLD & FLU

Acetaminophen (Pain reliever/fever reducer)
Dextromethorphan HBr (Cough suppressant)
Doxylamine succinate (Antihistamine)

Multi-Symptom Relief

- Aches, Fever & Sore Throat
- Cough
- Sneezing, Runny Nose

Alcohol Free

12 FL OZ (354 mL)

**TAMPER EVIDENT: DO NOT USE IF PRINTED
NECK WRAP IS BROKEN OR MISSING**

PARENTS:

Learn About Teen Medicine Abuse

www.StopMedicineAbuse.org

BI-MART UNCONDITIONAL MONEY BACK GUARANTEE

If you are not completely satisfied with your BI-MART
QUALITY PRODUCT, regardless of the reason, return the
unused portion and your entire purchase price will be
cheerfully refunded.

*This product is not manufactured
or distributed by Procter & Gamble
distributor of Vicks® NyQuil®
Cold & Flu Nighttime Relief.

50844 ORG031801402

Distributed by:

BI-MART

Eugene, OR 97402

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BI-MART
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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

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COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:37835-524

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	650 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)		DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	green	Score		
Shape		Size		
Flavor	MINT (Eucalyptus)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37835-524-30	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part341	06/18/2018	

Labeler - Bi-Mart (027630078)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(37835-524) , pack(37835-524)

Revised: 5/2022

Bi-Mart